*i*CAHE JC Critical Appraisal Summary

Journal Club Details

Journal Club location	**Flinders Medical Centre**
JC Facilitator	**Cassandra Lawless**
JC Discipline	**Dietetics**

Question

N/A

Review Question/PICO/PACO

P: Patients with amyotrophic lateral sclerosis (ALS) who needed percutaneous endoscopic gastronomy (PEG) feeding

I: N/A

C: N/A

O: Survival time from PEG recommendation to death or tracheostomy.

Article/Paper

Fasano, A, Fini, N, Ferraro, D, Ferri, L, Vinceti, M, Errals & Mandrioli, J 2017, 'Percutaneous endoscopic gastrostomy, body weight loss and survival in amyotrophic lateral sclerosis: a population-based registry study', *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration*, vol. 18, no. 3-4, pp.233-242.

Please note: due to copyright regulations CAHE is unable to supply a copy of the critically appraised paper/article. If you are an employee of the South Australian government you can obtain a copy of articles from the DOHSA librarian.

Article Methodology: Prospective cohort registry study

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Ques No.	Yes	Can't Tell	No	Comments
1	✓			**Did the study address a clearly focused issue?** "To assess the role of percutaneous endoscopic gastrostomy (PEG) insertion, and its timing, on ALS survival, and to study prognostic factors of survival before and after PEG placement in a population-based setting."
2	✓			**Did the authors use an appropriate method to answer their question?** Yes, an observational, cohort study is adequate to measure the role of PEG insertion and timing on ALS survival. The study's objective did not attempt to generalize to all ALS populations by identifying that this research was designed specific to a set population. **Is it worth continuing?** YES
3	✓			**Was the cohort recruited in an acceptable way?** The study recruited consecutive patients over a set period of time and identified inclusion and exclusion criteria. The study's objective identified that this study was for a set population and recruitment reflected this aim. "The study included all consecutive patients diagnosed with ALS according to EEC-R (16) between 1 January 2009 and 31 December 2013, who were resident in the Emilia Romagna Region and who were considered to 'need' supplemental tube feedings as explained above (in the assessment section)."

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4	✓			**Was the exposure accurately measured to minimize bias?** *Assessment* "At each clinical follow-up visit, investigators assessed ALS Functional Rating Scale (ALSFRS-R), respiratory function values, height and body weight (measured by a dietician or a nutritionist), and need for procedures (PEG, NIV, IV). Each participant was followed up until death or until 31 December 2014 at the latest. 'Gastrostomy need' was defined by a score of 1 ('needs supplemental tube feedings') at item 3 (swallowing) of the ALSFRS-R at follow-up visits. The 'need for supplemental tube feedings' was identified in the presence of a moderate-severe bulbar impairment with aspiration risk or malnutrition (weight loss >10%), but also taking into account the patient's respiratory function and general condition in accordance with international guidelines (2). Furthermore, we defined PEG placement time as 'early' if it occurred within one month from the first recognised need or 'late' if it occurred after one month (for any reason). This interval was chosen since regional guidelines for ALS management suggest performing PEG within one month from its recognised need and patients' acceptance, and since the median time from the moment PEG was first needed to PEG placement was one month."
5		✓		**Was the outcome accurately measured to minimize bias?** The authors did describe what qualified as a need for PEG placement (see *Assessment*). The authors defined PEG placement time in the *Assessment* section of the report too but the article did not describe how often the need for a PEG was assessed. Given the primary outcome was the time from PEG recommendation to death or tracheostomy, if the assessment for PEG need was not consistent, there is a risk of measurement bias.
6	✓			**Have the authors identified all important confounding factors?** The authors identified that age, weight, progression of disease, respiratory function and PEG insertion all had effects on the results. They identified means to control for these confounders and identified that their cohort was largely older, had more advanced disease and had significantly lower respiratory capacity. **Have they taken account of the confounding factors in the design and/or analysis?** "The main strength of this study is represented by the study population, deriving from a large register, and which includes only patients needing PEG in the analyses, thus eliminating the bias of using only patients referred to tertiary centres or patients accepting PEG. The weaknesses of the study is represented by the observational design, with its inherent limitations, by the possibility of a 'treatment indication bias', as the assignment to PEG and non-PEG groups was not random, by missing data, especially for patients in the advanced stages of the disease. Moreover, we did not collect data on PEG-related complications, nutritional support after PEG, and QoL."

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7	✓			**Was the follow up of subjects complete enough?** Patients were followed up until death or until the end of the study. Given the high mortality post PEG placement, the four year study duration (Jan 2009 – Dec 2013) captured multiple descriptions of outcomes from PEG recommendation to death.
8				**What are the results of this study?** "Overall, at 30 days after PEG, 14 patients had died. Tracheostomy-free survival at one month after PEG was 89.60%; 55% of patients survived six months, 39% 12 months, 25% 24 months, and 24% 48 months after PEG placement. Median survival from time of PEG insertion to death or tracheostomy was eight months (95% CI 5–12). At univariate analysis, sex, and less overall weight loss from diagnosis to time of PEG placement (% BMI), were associated with significantly better survival. Weight measure after PEG placement at three and six months were available only for 81 and 59 patients, respectively. Only 14 (17.28%) and 16 (27.12%) patients did not lose weight at three and six months after PEG placement. Mean BMI variations at three and six months from PEG placement were –0.13 (S.D.= 1.24) and –0.29 (S.D. = 1.70), respectively. In this small sample, tracheostomy-free survival after PEG was influenced by the presence of weight loss following PEG insertion (at six months: Hazard Ratio (HR) 2.51, 95% CI 1.09–5.81, p=0.03) (Graph 2). In conclusion, our study, although with several limitations, suggests a gain of tracheostomy-free survival from PEG recommendation for patients who underwent PEG placement, and, among patients who underwent PEG, a greater survival if PEG was inserted before a significant weight loss occurred, and if nutritional support avoided further weight loss."
9				**How precise are the results?** P values were reported as too were 95% confidence intervals.
10	Journal Club to discuss			**Do you believe the results?**
11				**Can the results be applied to the local population?** **CONTEXT ASSESSMENT (please refer to attached document)** – *Infrastructure* – *Available workforce (? Need for substitute workforce?)* – *Patient characteristics* – *Training and upskilling, accreditation, recognition* – *Ready access to information sources* – *Legislative, financial & systems support* – *Health service system, referral processes and decision-makers* – *Communication* – *Best ways of presenting information to different end-users* – *Availability of relevant equipment* – *Cultural acceptability of recommendations* – *Others*

12		**Were all important outcomes considered?**
13		**Are the benefits worth the harms and costs?**
14		**What do the study findings mean to practice (i.e. clinical practice, systems or processes)?**
15		**What are your next steps?** ***ADOPT, CONTEXTUALISE, ADAPT*** **And then (e.g. evaluate clinical practice against evidence-based recommendations; organise the next four journal club meetings around this topic to build the evidence base; organize training for staff, etc.)**
16		**What is required to implement these next steps?**

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